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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,455	02/10/2004	Robert L. Diaz	2385.010	3593

21917 7590 11/29/2007

MCHALE & SLAVIN, P.A.
2855 PGA BLVD
PALM BEACH GARDENS, FL 33410

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,455	DIAZ, ROBERT L.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse Group III, claims 13-20, drawn to an intra-operative method for essentially eliminating pain associated with a surgical procedure performed in a patient weighing less than or greater than 160 pounds comprising the steps set forth in claims 13-20, classified in class 514, subclass 570 (and over 160 pounds as set forth in claim 17) is acknowledged.

Accordingly, claims 13-20 are being examined on the merits and claims 1-12 are withdrawn from consideration because they are non-elected invention.

Specification

The use of the trademark DARVOCET-100 and VICODIN have been noted in this application. (e.g. page 21, lines 22 and 23,page 22, lines 9-10, line 23). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 14 and 18 recite the limitation "medical solution" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Al Kaisy A et al. (1998) in view of Gennery (U.S.Patent No. 5,919,804) and further in view of Jessup et al. (U.S.Patent No. 4,405,322).

Al Kaisy A et al. teach an excellent analgesic effect of interscalene block using low-dose bupivacaine with epinephrine for outpatient arthroscopic shoulder surgery. (title, text). Al Kaisy A et al. teach that postoperative pain can be effectively relieved by a very low dose of bupivacaine. Al Kaisy A et al. teach that interscalene brachial plexus block with 10ml 0.125% bupivacaine with epinephrine provides excellent analgesia following shoulder surgery when combined with general anesthesia. Al Kaisy A et al. teach that the advantages of this technique are reduced opioid consumption, minimal sensory and motor dysfunction, and shortened time of hospital recovery. Al Kaisy A et al. teach that ketorolac 10mg was also employed in the procedure. (see disclosure).

Al Kaisy A et al. do not teach the employment of Levobupivicaine, specific amounts and dilutions of the agents, employment of ketorolac in injectable formulation and the injection device set forth in claim 14.

Gennery teaches the use of levobupivicaine in a surgical procedure. (abstract). Gennery teaches that racemic bupivacaine is cardiotoxic, having depressant electrophysiological and mechanical effects on the heart. Gennery teaches that it has been suggested that levobupivicaine is less cardiotoxic than racemic bupivacaine. Gennery teaches that administration of levobupivicaine in post-operative analgesic, small volume should be administered for an effective, safe, long-acting anesthetic effect. (abstract, column 1, lines 10-57).

Jessup teaches anesthesia device comprising elongated cannula having a lumen, and a plurality of apertures in a distal portion of the cannula communicating with the lumen. The device has a hollow adapter secured to a proximal end of the cannula. (abstract, figure).

It would have been obvious to one of ordinary skill in the art to modify the method of Al Kaisy A et al. and employ levobupivicaine instead of bupivacaine for an intra-operative for eliminating pain in a surgical procedure because levobupivicaine is safe and effective for reducing pain in a surgical procedure compared to bupivacaine because it is less cardiotoxic than bupivacaine as taught by Gennery. One would have been motivated to make such a modification in order to reduce a depressant electrophysiological and mechanical effect on the heart that can be resulted from the employment of bupivacaine. With regard to dilution of the agents to be employed and employment of ketorolac in injectables rather than oral administration taught by Al Kaisy A et al. are all obvious because optimizing dilution for the injectable formulation is routinely performed during reconstitution and preparation of anesthetic agents needed for a surgical procedure. One would have been motivated to incorporate ketorolac in injectables among with levobupivicaine in order to administer with levobupivicaine injection in a single injection route. Further, to employ the injectable device to administer small amounts of anesthetic solution to optimize the therapy is obvious because Jessup teaches that anesthetic device comprising elongated cannula having a lumen and a plurality of apertures in a distal portion of the cannula is routinely employed in the anesthetic procedure. One would have been motivated to employ such device in

order to effectively administer small volume of the obvious anesthetic solution in order to achieve an effective, safe and long-acting anesthetic effect that is desired in levobupivicaine in post-operative analgesic procedure.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Primary Examiner
Art Unit 1617

Jmk
November 13, 2007